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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,055

08/21/2003

Douglas A. Devens JR.

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/645,055	<b>Applicant(s)</b> DEVENS ET AL.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-26 and 39-44 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 13, 15, 16, 18-26 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8, 10, 12, 14, 17, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This is the initial Office Action following the Request for Continued Examination based on the 10/645055 application filed August 21, 2003. Claims 1-5, 8, 10, 12, 14, 17, 43 and 44 as amended are currently pending and considered below.

#### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: in line 2, the phrase "a balloon comprising" should be followed by a colon -- : --. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The above claim recites the limitation "the portions", which the examiner notes can apply either to the first and second portions taken together, the cone and body portions taken together, or could also cover some combination thereof. For purposes of examination, the examiner has interpreted "the portions" in claim 14 to mean "the first and second portions".

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

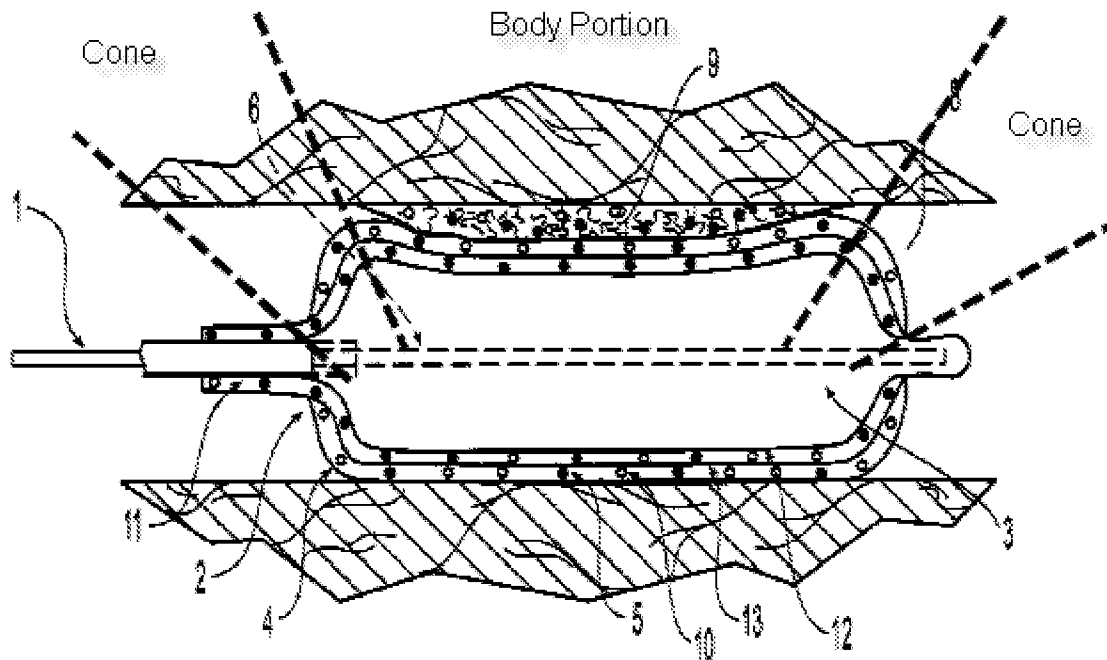
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-5, 8, 10, 12, 14, 17, 43, and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over USPN 6,364,856 B1 to Ding et al.

Regarding claims 1-3, 8, 10, 12, and 14, Ding et al disclose a medical device comprising a balloon (3) comprising a first portion having a first length (2), and a second portion disposed on the first portion having a second length (4); wherein the first portion varies in thickness along the first length and the second portion varies in thickness along the second length (Figs. 2a, 2b; see right hand side), wherein the balloon has a body portion and a cone portion and wherein the first portion has a great thickness at the body portion than at the cone portion (Fig. 2b; the body portion of the first portion is

Art Unit: 3763

thicker than the tapered portion of the cone; see Fig. 2b reproduced below for clarification).



*Fig. 2b*

Ding et al further disclose that the first and second portions have different compositions (the first portion is a reservoir, the second is a sponge material), that the second portion is disposed substantially entirely on the first portion, that the thickness of the first and second portions is generally constant in the cone portion (the tapering of the portions takes place only at the most extreme end of the cone portions, and therefore the thickness is maintained along substantially the entire length), and that the portions extend substantially the entire length of the balloon (Figs. 2a and 2b).

Regarding claims 4, 5, and 17, Ding et al do not explicitly teach or disclose that the first and second portions have different hardness, that the second portion is softer than the first portion, or that the cone portion is more flexible than the body portion.

Art Unit: 3763

However, these properties of the first and second portions are either inherent or obvious to one having ordinary skill in the art at the time the invention was made, as material selection from those commonly used in the art is considered obvious. In addition, because the first and second portions taper sharply at the end of the cone portion, the examiner believes this would impart additional flexibility to the cone portion because, in general, when the thickness of a material is decreased, its flexibility is increased.

Regarding claims 43, Ding et al disclose a medical balloon (3) comprising a plurality of layers including a first layer formed from a first material (2) and a second layer formed from a second material different than the first material (4), wherein the first layer varies in thickness axially along the balloon (Figs. 2a and 2b), and includes a first thickness adjacent a waist portion of the balloon (see right terminus of the first layer at the right-hand side of Figs. 2a and 2b), and a second thickness greater than the first thickness adjacent a body portion of the balloon (Figs. 2a and 2b), and wherein the second layer varies in thickness axially along the balloon (Figs. 2a and 2b).

Regarding claim 44, Ding et al also disclose that the balloon includes a tapered portion (see “cone” in the labeled Fig. 2b reproduced above), but do not explicitly teach or disclose that the body and tapered portions have different stiffness. Because the first and second layers taper sharply at the end of the tapered portion, the examiner believes this would impart additional flexibility to the tapered portion because, in general, when the thickness of a material is decreased, its flexibility is increased, and therefore its stiffness is decreased.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell  
Examiner, AU 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763